

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

MILLENIUM BIOLOGIX, LLC)	
)	
Plaintiff,)	
)	Civil Action No. 13-CV-3084
v.)	
)	Hon. Judge Virginia M. Kendall
BAXTER HEALTHCARE CORP.)	
APATECH, INC., AND)	
APATECH, LTD.)	
)	
Defendants.)	

SECOND AMENDED COMPLAINT

This is an action for patent infringement in which Millenium Biologix, LLC (“Millenium” or “Plaintiff”) makes the following allegations against Baxter Healthcare Corp. (“Baxter”), ApaTech, Inc., and ApaTech, Ltd. (collectively, “Defendants”).

PARTIES

1. Plaintiff is a limited liability company organized under the laws of the State of Nebraska. Plaintiff maintains its principal place of business at 2323 S. 171st Street, Suite 106, Omaha, Nebraska 68130.

2. Upon information and belief, Defendant Baxter is, and at all relevant times mentioned herein was, a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 1 Baxter Pkwy, Deerfield, IL 60015. Baxter manufactures for sale and/or sells healthcare products in the United States and, more particularly, in the Northern District of Illinois. Defendant Baxter is a wholly-owned subsidiary of Baxter International, Inc. Baxter may be served with process by serving its registered agent, The

Corporation Trust Company, located at Corporation Trust Center 1209 Orange St., Wilmington, Delaware 19801.

3. Upon information and belief, Defendant ApaTech, Inc. is, and at all relevant times mentioned herein was, a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 1 Baxter Pkwy # Df3-3e, Deerfield, IL, 60015. ApaTech, Inc. manufactures for sale and/or sells healthcare products in the United States and, more particularly, in the Northern District of Illinois. ApaTech, Inc. may be served with process by serving its registered agent, The Corporation Trust Company, located at Corporation Trust Center 1209 Orange St., Wilmington, Delaware 19801.

4. Upon information and belief, Defendant ApaTech, Ltd. is, and at all relevant times mentioned herein was, a corporation organized and existing under the laws of the United Kingdom with a principal place of business at 370 Centennial Ave., Centennial Park, Elstree, Hertfordshire, WD6 TJ, United Kingdom. ApaTech, Ltd. manufactures for sale and/or sells healthcare products in the United States and, more particularly, in the Northern District of Illinois. ApaTech, Ltd. is a wholly-owned subsidiary of Baxter Holding B.V., which is a wholly-owned subsidiary of Baxter Global Holdings II Inc., which is a wholly-owned subsidiary of Baxter Healthcare Corporation of Puerto Rico, which is a wholly-owned subsidiary of Baxter Sales and Distribution Corp, which is a wholly-owned subsidiary of Baxter World Trade Corp., with preferred stock held by Defendant Baxter. Baxter World Trade Corp. is a wholly-owned subsidiary of Baxter International Inc. Defendant ApaTech, Ltd. was acquired by Baxter B.V. (and consequently, Defendant Baxter) in or around March 2010. ApaTech, Ltd. may be served with process by serving its controlling parent corporation, Defendant Baxter, which may be

served with process by serving its registered agent, CT Corporation System, 208 SO LaSalle St., Suite 814, Chicago, IL, 60604.

JURISDICTION AND VENUE

5. This is an action for violation of the patent laws of the United States, Title 35, United States Code, more particularly, 35 U.S.C. §§ 271 *et seq.*

6. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over the Defendants. Defendants have conducted and do conduct business within the State of Illinois. Defendants, directly or through intermediaries (including distributors, retailers, and others), ship, distribute, offer for sale, sell, and advertise its products in the United States, the State of Illinois, and the Northern District of Illinois. Upon information and belief, each Defendant has purposefully and voluntarily placed one or more of its infringing products, as described below, into the stream of commerce with the expectation that they will be used in medical treatments in the Northern District of Illinois. Upon information and belief, these infringing products have been and continue to be purchased by consumers in the Northern District of Illinois. Defendants have committed the tort of patent infringement within the State of Illinois and, more particularly, within Northern District of Illinois.

8. Venue is proper in the Northern District of Illinois under 28 U.S.C. §§ 1391 and 1400(b).

PATENT INFRINGEMENT COUNTS

9. Plaintiff refers to and incorporates all preceding paragraphs as though fully set forth herein.

10. United States Patent No. RE 41,251 (“the ‘251 Patent”), entitled “Synthetic Biomaterial Compound of Calcium Phosphate Phases Particularly Adapted for Supporting Bone Cell Activity” was duly and legally issued by the United States Patent and Trademark Office on April 20, 2010, after full and fair examination. The ‘251 Patent is a reissued patent of United States Patent No. 6,323,146 (“the ‘146 Patent”). The ‘146 Patent was duly and legally issued by the United States Patent and Trademark Office on November 27, 2001. Plaintiff is the exclusive licensee of all rights, title, and interest in and to the ‘251 Patent and possesses all rights of recovery under the ‘251 Patent, including the right to recover damages for past infringements. A true and correct copy of the ‘251 Patent is attached as Exhibit A.

11. United States Patent 6,585,992 (“the ‘992 Patent”), entitled “Synthetic Biomaterial Compound of Calcium Phosphate Phases Particularly Adapted for Supporting Bone Cell Activity” was duly and legally issued by the United States Patent and Trademark Office on July 1, 2003, after full and fair examination. Plaintiff is the exclusive licensee of all rights, title, and interest in and to the ‘992 Patent and possesses all rights of recovery under the ‘992 Patent, including the right to recover damages for past infringements. A true and correct copy of the ‘992 Patent is attached as Exhibit B.

12. Upon information and belief, Defendants manufacture, use, sell, offer to sell and/or distribute healthcare products, including, but not limited to, Actifuse Bone Graft Substitute. Actifuse is a bone void filler intended for orthopedic applications as filler for gaps and voids that are not intrinsic to the stability of the bony structure. Actifuse is sold in several different forms, found under various names including ABX, Granules, Microgranules, MIS, and Shape. Actifuse is implanted by medical professionals in vivo to fill bone defects.

13. On or around March 30, 2007, ApaTech, Ltd. sent a letter to Millenium Biologix, Inc. (“MBI”), informing MBI of ApaTech, Ltd.’s intent to file requests for reexam of the ‘146 Patent and the ‘992 Patent. Exhibit C.

14. On or around March 1, 2010, Baxter issued a press release entitled “Baxter to Acquire All Outstanding Equity of ApaTech, Including Actifuse.” The press release noted that Baxter International, Inc. purchased ApaTech for “total consideration of up to \$330 million.” The press release emphasizes “[a]s a result of the acquisition, Baxter will acquire ACTIFUSE, a silicate substituted calcium phosphate synthetic bone graft material”

15. Defendants market Actifuse on the website www.actifusebonegraft.com/us. Actifuse is advertised as a bone void filler and a bone grafting material to be implanted into bone. Defendants distribute Actifuse product information entitled “Information For Use” (“IFU”). Defendants’ IFU’s are directed to medical professionals and describe the products, provide the indications for use, and provide instructions to medical professionals on how to implant Actifuse in bone. Exhibits D - H.

COUNT 1: INFRINGEMENT OF U.S. PATENT NO. RE 41,251

16. Plaintiff refers to and incorporates all preceding paragraphs as though fully set forth herein.

17. All Actifuse products infringe at least claims 1 and 6 of the ‘251 Patent.

18. Defendant ApaTech, Ltd. had notice of the ‘251 Patent by virtue of having actual notice of the ‘146 Patent (the original patent to the Reissued ‘251 Patent) at least as early as March 30, 2007, as shown by the letter to MBI indicating ApaTech, Ltd.’s intent to request reexamination for the ‘146 Patent and the ‘992 Patent. On information and belief, Defendants Baxter and ApaTech, Inc. have had actual notice of the ‘251 Patent prior to the filing and service

of this lawsuit, given their corporate relationship with ApaTech, Ltd. ApaTech Ltd. is now an acquired affiliate of Baxter and as such, prior knowledge of ApaTech Ltd. is imputed to Baxter. Additionally, Baxter's due diligence of ApaTech, Ltd. leading up to its purchase of ApaTech, Ltd. would have revealed the March 30, 2007 letter and any underlying concerns. In any event, Defendants Baxter and ApaTech, Inc. have actual notice of the '251 Patent at least as early as the filing and service of the Original Complaint on April 24, 2013. (Dkt. 1).

19. Upon information and belief, Defendants are infringing at least claims 1 and 6 of the '251 Patent under 35 U.S.C. § 271(a) by performing, without authority, one or more of the following acts: making, using, importing, offering to sell, and selling within the United States the patented invention of one or more claims of the '251 Patent.

20. Upon information and belief, Defendants' infringement of the '251 Patent has been knowing and willful.

21. Plaintiff has been damaged as a result of Defendants' infringing conduct. Defendants are, thus, liable to Plaintiff in an amount that adequately compensates Plaintiff for their infringement, which, by law, cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 § U.S.C. 284.

22. Plaintiff is in compliance with the requirements of 35 U.S.C. § 287, and is entitled to past damages. From the date of six years before this suit was filed up to date of filing this suit, there were no authorized sales of commercial products embodying one or more claims of the '251 Patent.

23. As a result of Defendants' acts of infringement, Plaintiff has suffered and will continue to suffer damages in an amount to be proved at trial.

COUNT 2: INFRINGEMENT OF U.S. PATENT NO. 6,585,992

24. Plaintiff refers to and incorporates all preceding paragraphs as though fully set forth herein.

25. Implantation of Actifuse in bone infringes at least claims 1, 2, 9 and 18 of the '992 Patent.

26. ApaTech, Ltd. had notice of the '992 Patent by virtue of having actual notice of the '992 Patent at least as early as March 30, 2007, as shown by the letter to MBI indicating ApaTech, Ltd.'s intent to request reexamination for the '146 Patent and the '992 Patent. On information and belief, Defendants Baxter and ApaTech, Inc. have had actual notice of the '992 Patent prior to the filing and service of this lawsuit, given their corporate relationship with ApaTech, Ltd. ApaTech Ltd. is now an acquired affiliate of Baxter and as such, prior knowledge of ApaTech Ltd. is imputed to Baxter. Additionally, Baxter's due diligence of ApaTech, Ltd. leading up to its purchase of ApaTech, Ltd. would have revealed the March 30, 2007 letter and any underlying concerns. In any event, Defendants Baxter and ApaTech, Inc. have actual notice of the '992 Patent at least as early as the filing and service of the Original Complaint on April 24, 2013. (Dkt. 1).

27. ApaTech, Ltd's March 30, 2007, letter concerning its planned reexam of the '992 patent shows that ApaTech, Ltd. had knowledge of the asserted '992 patent claims and that ApaTech, Ltd acts, such as its teachings to physicians of how to use the Actifuse product as well as its sales of the Actifuse product, would result in infringement of those claims.

28. Upon information and belief, Defendants are infringing at least claims 1, 2, 9 and 18 of the '992 Patent under 35 U.S.C. § 271(b) by, without authority, selling and offering to sell Actifuse in the U.S., and then encouraging medical professionals to implant Actifuse in human

bone in an infringing manner, and knowing that the medical professionals indeed are implanting Actifuse as recommended by Defendants.

29. Specifically, in the IFUs packaged with Actifuse, Defendants instruct medical professionals in the “Indications for Use” section that Actifuse “is a bone void filler intended only for orthopedic applications as a filler of gaps and voids that are intrinsic to the stability of the bony structure.” Likewise, in the “Instructions for Use” section, Defendants instruct medical professionals how to prepare Actifuse for implantation in bone and to “implant” Actifuse in bone. Exhibits D - H. ApaTech and Baxter are instructing medical professionals to use Actifuse in an infringing manner, medical professionals are directly infringing claims of the ‘992 patent by following the Defendants’ instructions, and the Defendants have and have had actual knowledge of the ‘992 patent and understood the impact of the ‘992 patent claims to Actifuse, otherwise Defendants would not have threatened reexam in March 2007. Since that time Defendants have not modified the Actifuse products so as to avoid infringement or modified their instructions to medical professionals on how to use Actifuse in an infringing manner.

30. Upon information and belief, Defendants are infringing at least claims 1, 2, 9 and 18 of the ‘992 Patent under 35 U.S.C. § 271(c) by, without authority, offering to sell and selling within the United States Actifuse, knowing that Actifuse infringes the asserted patent claims and that Actifuse is not a staple article and has no substantial noninfringing uses, based at least in part on the fact that in March 2007 Defendants understood the ‘992 patent claims applied to the Actifuse products, hence the threat to MBI to file a reexam, and Defendants have made no changes to Actifuse since March 2007 to avoid infringements.

31. Specifically, in the IFUs packaged with Actifuse, Defendants instruct medical professionals in the “Indications for Use” section that Actifuse “is a bone void filler intended

only for orthopedic applications as a filler of gaps and voids that are intrinsic to the stability of the bony structure.” Likewise, in the “Contraindications for Use” section, Defendants instruct medical professionals that Actifuse “is not designed for any use except as indicated.” Exhibits D - H.

32. Upon information and belief, Defendants’ infringement of the ‘992 Patent has been knowing and willful.

33. Plaintiff has been damaged as a result of Defendants’ infringing conduct. Defendants are, thus, liable to Plaintiff in an amount that adequately compensates Plaintiff for their infringement, which, by law, cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 § U.S.C. 284.

34. As a result of Defendants’ acts of infringement, Plaintiff has suffered and will continue to suffer damages in an amount to be proved at trial.

PRAYER FOR RELIEF

Plaintiff prays for the following relief:

- A. A judgment that Defendants have directly infringed the ‘251 Patent as alleged herein;
- B. A judgment that Defendants’ infringement of the ‘251 Patent was willful.
- C. A judgment that Defendants have indirectly infringed the ‘992 Patent as alleged herein;
- D. A judgment that Defendant’s infringement of the ‘992 Patent was willful.
- E. A judgment and order requiring Defendants to pay Plaintiff compensatory damages in an amount no less than a reasonable royalty under 35 U.S.C. § 284;

F. A judgment and order requiring Defendants to pay Plaintiff pre-judgment and post-judgment interest on the damages awarded;

G. A judgment and order that Defendants pay Plaintiff an on-going royalty for future acts of infringement if appropriate, at a rate determined by the jury or the Court;

H. An judgment and order that Defendants pay Plaintiff treble damages for willful infringement;

I. A judgment that this is an exceptional case and order that Defendants pay Plaintiff's attorney fees under 35 U.S.C. § 285; and

J. Any and all other relief as the Court deems just and equitable.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands that all issues be determined by a jury.

Dated: October 1, 2013

Respectfully submitted,

/s/ Gary M. Miller

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on October 1, 2013, the foregoing **SECOND AMENDED COMPLAINT** was filed with the Clerk of Court using the CM/ECF system and a copy was served on the following by electronic transmission:

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